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ATTACHMENT 5

510(k) SUMMARY

This 510(k) summary of safety and effectiveness for the Adept UltraLite 532 Laser is submitted in accordance with the requirements of SMDA 1990 and follows Office of Device Evaluation guidance concerning the organization and content of a 510(k) summary.

Applicant: Adept Medical Concepts, Inc.

Address: 29816 Avenue De Las Banderas
Rancho Santa Margarita, CA 92688

Contact person: Mr. Jerry McFarland
President
jmcfarland@adeptmedicalconcepts.com

Telephone: 949-635-9238
949-635-9106 (fax)

Preparation Date: August 2004
(of the Summary)

Device Name: Adept UltraLite 532 Laser

Common Name: Surgical laser

Classification: Laser surgical instrument for use in general and plastic surgery and dermatology

Class II medical device; (21 CFR 878.4810).

Product Code: GEX
Panel: 79

Predicate device: The Laser System BeautyStar 532 Laser (K021975).

Device description: The Adept UltraLite 532 Laser is a diode laser which emits coherent light at 532 nm.

Indications for Use: The ADEPT ULTRALITE 532 LASER is intended for vaporization and photocoagulation of vascular and pigmented lesions in soft tissue

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Examples include:

Telangiectasia
Spider Naevi
Angioma
Hemangioma
Leg veins (small, superficial)
Epidermal Naevi
Lentigines (solar and senile)
Verrucae Vulgares (Warts)
Cherry Angioma
Port Wine Stain

Performance Data: None required. The claim of substantial equivalence is based on comparisons of specifications/characteristics and intended uses of the UltraLite 532 and the claimed predicates, i.e., the BeautyStar 532 and DioLite 532 lasers.

Conclusion: Based on the information in the notification Adept Medical Concepts, Inc., believes that the Adept UltraLite 532 Laser as described in this notification is substantially equivalent to the claimed predicates for the indications for use as listed above.

Name of Manufacturer: Lasering, SRL, Modena, Italy; **marketed by Adept Medical Concepts, Inc.**

Laser Model Name and Number: Adept Ultralight 532

Laser Type: (Circle all that apply)

Alexandrite, Argon, CO₂, Copper-Vapor, Diode, Dye, Nd:YAG, Erbium, Hol: YAG, Krypton, Ruby, KTP/532, Excimer, HENE, Accessory, Other _____

Indications in this application: Vaporization and photocoagulation of vascular and pigmented lesions in soft tissue. Examples include: Telangiectasia, Spider Naevi, Angioma, Hemangioma, Leg veins (small, superficial-see above), Epidermal Naevi, Lentigines (solar and senile), Verrucae Vulgares (Warts), Cherry Angioma, Port Wine Stain.

FDA Document Control Number: K042496

FDA Product Code: 79 GEX, Class II

Reviewer Computer Initials: ABC

Date of Clearance Letter: 10/22/04

Basis of Approval: (Circle all that apply)

Predicate Devices (PD), Clinical Data (CD), Animal Data (AD), Specifications (SPECS), Bench Test Data (BTD), Historical Information (HI), Other _____

Description of Laser: The Ultralight 532 is a diode pumped solid state frequency doubled laser appliance.

Operation Modes: (Circle all that apply)

CW, Pulsed, Q-Switched, Mode Locked, Contact, Free Beam, Other or continuous

Wavelength in Nanometers: 532

Power/Energy Range (Watts): 1-5 W

Pulse Width: 10 ms

Repetition Rate: 0.3-100 Hz

Delivery System: Quartz Fiber with Hand piece

Comments:



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Jerry McFarland
President
Adept Medical Concepts, Inc.
29816 Avenue De Las Banderas
Rancho Santa Margarita, California 92688

Re: K042496

Trade/Device Name: ADEPT ULTRALITE 532 LASER

Regulation Number: 21 CFR 878.4810

Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology

Regulatory Class: II

Product Code: GEX

Dated: September 10, 2004

Received: September 17, 2004

Dear Mr. McFarland:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K042496

Device Name: ADEPT ULTRALITE 532 LASER

Indications for Use Statement:

The ADEPT ULTRALITE 532 LASER is intended for vaporization and photocoagulation of vascular and pigmented lesions in soft tissue.

Examples include:

Telangiectasia
Spider Naevi
Angioma
Hemangioma
Leg veins (small, superficial - see above)
Epidermal Naevi
Lentigines (solar and senile)
Verrucae Vulgares (Warts)
Cherry Angioma
Port Wine Stain

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Prescription Use ☒
(Per 21 CFR 801.109)

Miriam C. Borost Over-The Counter Use
(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

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510(k) Number K042496